



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
HEADQUARTERS, US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
810 SCHREIDER STREET
FORT DETRICK, MARYLAND 21702-5000

February 25, 2019

Office of the Secretary of the General Staff
FOIA #FA-19-0008

Dr. Remington Nevin
MuckRock News
DEPT MR 63042
411A Highland Avenue
Somerville, MA 02144-2516

Dear Dr. Nevin:

This is in response to your December 11, 2018 Freedom of Information Act request for documents concerning and related to presentations made by U.S. Army Medical Research and Materiel Command (USAMRMC) and subordinate staff to the U.S. Food and Drug Administration Antimicrobial Drugs Advisory Committee Meetings held July 12, 2018 and July 26, 2018. A representative from the U.S. Army Medical Materiel Development Activity (USAMMDA) presented for USAMRMC at the Open Public Hearing portion of the July 26, 2018, U.S. Food and Drug Administration Antimicrobial Drugs Advisory Committee meeting (Encl). On July 12, 2018 the same representative attended the meeting, but no USAMRMC presentations were provided during that meeting. This FOIA request has been granted in full.

Should you have any questions pertaining to this request, I may be reached at (301)-619-7438 or email shalli.l.keller.civ@mail.mil

Respectfully,

A handwritten signature in black ink, reading "Shelli L. Keller", is positioned above the typed name and title.

Shelli L. Keller
Staff Action Control Officer
Freedom of Information Act Officer
U.S. Army Medical Research and
Material Command

Enclosure

Keller, Shalli L CIV USARMY MEDCOM USAMRMC (US)

From: Keller, Shalli L CIV USARMY MEDCOM USAMRMC (US)
Sent: Tuesday, February 26, 2019 3:27 PM
To: '65313-57791137@requests.muckrock.com'
Subject: FOIA Request FA-19-0008
Attachments: SKM_C554e19022607560.pdf; USAMMDA_TQ_ACM_FINAL_revised.pdf; [Non-DoD Source] Freedom of Information Act Request: Tafenoquine Present... (5.73 KB)
Signed By: shalli.l.keller.civ@mail.mil

Good Afternoon,

This is in response to your FOIA request for documents concerning and related to presentations made by USAMRMC and subordinate staff to the U.S. Food and Drug Administration Antimicrobial Drugs Advisory Committee Meetings held July 12, 2018 and July 26, 2018. This request is attached and has been granted in full. If you have any additional questions, please let me know. A copy of this request will be sent in the mail.

Thank you,

Shalli L. Keller
Staff Action Control Officer
USAMRMC - Fort Detrick, MD
301-619-7118

Keller, Shalli L CIV USARMY MEDCOM USAMRMC (US)

From: 65313-57791137@requests.muckrock.com
Sent: Tuesday, December 11, 2018 10:52 AM
To: USARMY Ft Detrick MEDCOM USAMRMC List FOIA MPMC
Subject: [Non-DoD Source] Freedom of Information Act Request: Tafenoquine Presentations to the U.S. FDA Antimicrobial Drugs Advisory Committee

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U.S. Army Medical Research and Materiel Command FOIA Office
810 Schreider Street
Frederick, MD 21702-5000

December 11, 2018

Ms. Shalli Keller
Staff Action Control Officer
U.S. Army Medical Research and Materiel Command
Email: shalli.l.keller.civ@mail.mil
Tel: 301-619-7118

c/o
CDR USAMRMC
810 Schreider Street
Fort Detrick, MD 21702-5000

Re: FOIA Request

Dear Ms. Keller,

This is a request under the Freedom of Information Act. I hereby request the following records:

Copies of all presentations made by USAMRMC and subordinate staff to the U.S. Food and Drug Administration Antimicrobial Drugs Advisory Committee Meetings, held July 12, 2018 and July 26, 2018, during the meetings' open public hearings.

The requested documents will be made available to the general public, and this request is not being made for commercial purposes.

In the event that there are fees, I would be grateful if you would inform me of the total charges in advance of fulfilling my request. I would prefer the request filled electronically, by e-mail attachment if available or CD-ROM if not.

Thank you in advance for your anticipated cooperation in this matter. I look forward to receiving your response to this request within 20 business days, as the statute requires.

Sincerely,

Dr. Remington Nevin

Filed via MuckRock.com

E-mail (Preferred): 65313-57791137@requests.muckrock.com

Upload documents directly: Caution-https://www.muckrock.com/accounts/agency_login/us-army-medical-research-and-material-command-4063/tafenoquine-presentations-to-the-us-fda-antimicrobial-drugs-advisory-committee-65313/?uuid-login=daeab52e-fb3f-43b9-8da2-89fc27d20ca8&email=USArmy.Detrick.MEDCOM-USAMRMC.List.FOIA-MRMC%40mail.mil#agency-reply

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For mailed responses, please address (see note):

MuckRock News

DEPT MR 65313

411A Highland Ave

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THE WAY



UNITED STATES ARMY MEDICAL

MATERIEL DEVELOPMENT ACTIVITY



FDA Antimicrobial Drugs Advisory
Committee Meeting

MAJ Victor Zottig, Product Manager
Pharmaceutical Systems Project Management Office
26 July 2018

Disclaimer

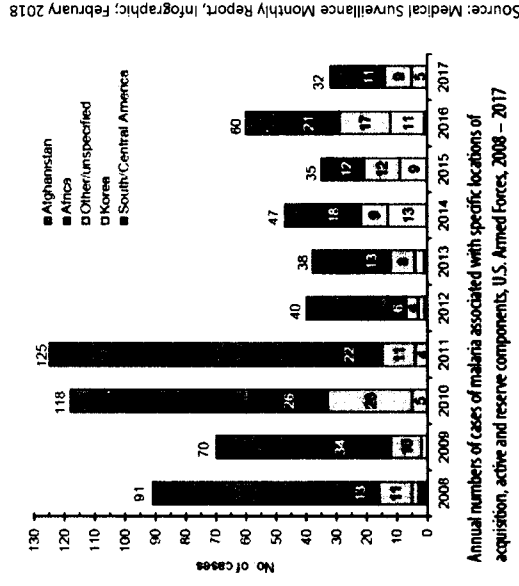
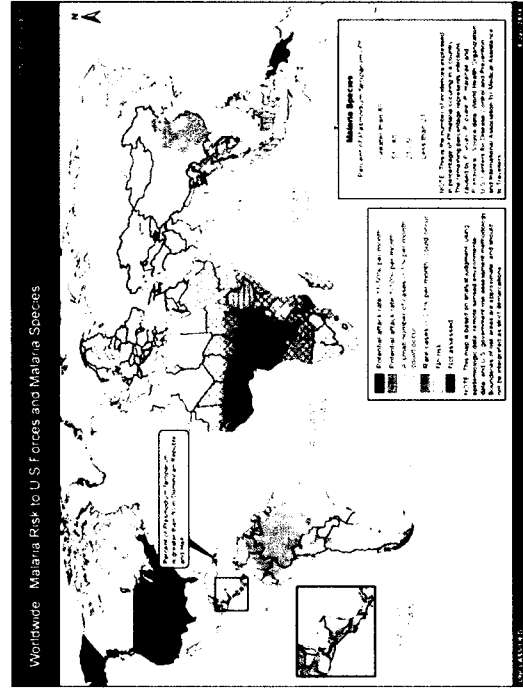
- The views expressed in the presentation are those of the author and do not necessarily represent the views of the U.S. Army or the Department of Defense (DoD).
- The author does not report any financial conflict of interest.
- Discussion of specific pharmaceutical products does not reflect an endorsement of those products. USAMMDA has a Cooperative Research and Development Agreement (statute 15USC 3710a) and Exclusive License Agreement with 60 Degrees Pharmaceuticals for the development of Tafenoquine for Malaria Prophylaxis.



Malaria Risks to Military Personnel

Malaria remains the number one infectious disease threat to deployed U.S. Military

- Resistance to current anti-malarial drugs is spreading
- Potential for poor chemoprophylaxis compliance with daily dosing
 - A drug with a longer half-life provides a flexible option during challenging operational conditions
- No licensed malaria vaccine
 - Lead vaccine candidates only moderately protect against only one species of malaria (*Plasmodium falciparum*)



DoD Policy for Malaria Prophylaxis*

Current FDA Approved Malaria Prophylactic Drug	Weekly Dosing	Effective against all disease stages?	7+ days post exposure treatment required?	Comments
Doxycycline	No	No	Yes	<ul style="list-style-type: none"> ✓ FDA approved; DoD first-line drug in chloroquine resistant areas × Must be taken at the same time every day × Increased photosensitivity and risk of vaginitis
Atovaquone - Proguanil	No	No	Yes	<ul style="list-style-type: none"> ✓ FDA approved; DoD first-line drug in chloroquine resistant areas × Resistance is developing to the drug
Mefloquine	Yes	No	Yes	<ul style="list-style-type: none"> ✓ FDA approved; for service members with intolerance or contraindications to the first-line drugs × FDA boxed warning for neuro-psychiatric adverse events
<ul style="list-style-type: none"> × Chloroquine - Due to widespread resistance, chloroquine is rarely used as a first line prophylaxis drug for Force Health Protection × Primaquine - Although listed in the CDC Yellow Book, primaquine is not FDA approved for prophylaxis and therefore not permitted for Force Health Protection 				

*HA Policy 13-002; Joint Health Affairs Memorandum for the Guidance on Medications for Prophylaxis of Malaria; 15 April 2013



Conclusion

- Malaria is debilitating and potentially fatal, and remains the top infectious disease threat to the U.S. Military
- There is an unmet medical need for a safe and effective weekly FDA approved prophylactic drug
- Current prophylactic options are insufficient
- The U.S. Army is committed to providing safe and effective solutions to protect the Warfighter

